K083745

FEB 17 2009

Paieon
Realizing Cardiac Imaging

510(k) SUMMARY- IC-PRO System

Submitter Name:	Paieon Inc.
Submitter Address:	747 Third Ave., 4th floor New York, NY 10017-2803
Contact Person:	Shahar Mandelboim
Phone Number:	+972 3 915 0000
Fax Number:	+972 3 901 2324
Date Prepared:	December 8, 2008
Device Trade Name:	The IC-PRO System
Device Common Name:	Cardiovascular Angiography Analysis System
Classification Name:	Angiographic x-ray system
Predicate Devices:	The IC-PRO (version 3.1) System cleared under K082907; The inReach system cleared for marketing under K081379; The Angio IVUS Mapping System cleared under K060483. The Ostial PRO Stent Positioning System cleared under K062192;
Device Description:	The IC-PRO (version 3.2) system is an image acquisition and processing modular software package designed as an add-on to conventional X-ray angiography systems. This system improves the output of cardiovascular angiography by providing software modules that assist in diagnosis, procedure planning, therapeutic stage and post deployment analysis. IC-PRO (version 3.2) provides quantitative data of vessel, left ventricular and stent dimensions enhances visualization and localizes device on predefined roadmaps.

Intended Use:

IC-PRO, an image acquisition and processing modular software package, is indicated for use as follows:

1. Assists in the evaluation of coronary lesions by enabling the creation of 3D images of coronary vessel segments based on two to three 2D angiography images obtained from single plane angiography. Provides quantitative information regarding the calculated dimensions of arterial segments based on the 3D image.
2. Performs quantitative analysis of the left ventricle based on left ventricular angiograms.
3. Enhances visualization of the stent deployment region and provides quantitative data based on manual stent tracings
4. Assist in device positioning by providing real time localization on predefined roadmaps.
5. To be used in-procedure in the catheterization lab and off-line for post-procedural analysis

It is intended for use by clinicians, technicians and research personnel.

Performance Standards: None

Performance Data: Testing included software validation and performance evaluation. The performance tests were made to evaluate the IC-PRO System and yield accuracy and precision results within the predetermined specifications with compare to results obtained by the marketed predicate devices.

Substantial Equivalence: The intended use and technological characteristics of the IC-PRO (version 3.2) are substantially equivalent to a combination of the intended use and technological characteristics of the predicate devices.

Conclusion: The testing reported in this 510(K) establishes that IC-PRO is substantially equivalent to the predicate devices and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Paieon, Inc.
% Mr. Shahar Mandelboim
Vice President R & D
Paieon Medical Ltd.
23 Hamelacha St., P.O.B 11355
Rosh Haayin 48091
ISRAEL

FEB 17 2009

Re: K083745
Trade/Device Name: The IC-PRO System
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI
Dated: December 11, 2008
Received: December 17, 2008

Dear Mr. Mandelboim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K083745

Paieon
Realizing Cardiac Imaging

Indications for Use

Device Name: **The IC-PRO System**

Indications for Use:

IC-PRO, an image acquisition and processing modular software package, is indicated for use as follows:

- Assists in the evaluation of coronary lesions by enabling the creation of 3D images of coronary vessel segments based on two to three 2D angiography images obtained from single plane angiography. Provides quantitative information regarding the calculated dimensions of arterial segments based on the 3D image.
- Performs quantitative analysis of the left ventricle based on left ventricular angiograms.
- Enhances visualization of the stent deployment region and provides quantitative data based on manual stent tracings
- Assist in device positioning by providing real time localization on predefined roadmaps.
- To be used in-procedure in the catheterization lab and off-line for post-procedural analysis

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K083745

(Posted November 13, 2003)